SERVED: May 6, 1999

NTSB Order No. EA-4761

UNITED STATES OF AMERICA
NATIONAL TRANSPORTATION SAFETY BOARD
WASHINGTON, D.C.

Adopted by the NATIONAL TRANSPORTATION SAFETY BOARD at its office in Washington, D.C. on the 28th day of April, 1999

Petition of

CINDY R. HUDSON

for review of the denial by the Administrator of the Federal Aviation Administration of the issuance of an airman medical certificate. Docket SM-4281

## OPINION AND ORDER

Petitioner has appealed the oral initial decision and order issued by Administrative Law Judge William A. Pope, II, on March 18, 1998, at the conclusion of an evidentiary hearing. In that decision, the law judge found that petitioner had failed to meet her burden of proving a satisfactory medical explanation for the seizures which she suffered on November 4, 1995. The law judge found petitioner unqualified to hold a third-class airman medical certificate under the provisions of Federal Aviation Regulation

<sup>&</sup>lt;sup>1</sup>An excerpt from the hearing transcript containing the initial decision is attached.

(FAR) Sections 67.309(a)(2) and (b).<sup>2</sup>

Petitioner, who represents herself in this appeal, argues, in essence, that the law judge erred by not accepting her explanation. Petitioner also disputes the testimony of the Administrator's expert witness concerning his assessment of petitioner's risk for seizure recurrence. The Administrator has filed a reply, urging the Board to affirm the law judge's initial decision. For the reasons that follow, petitioner's appeal is denied.

Petitioner is a student pilot. On October 26, 1995, she applied for a third-class airman medical certificate. During the course of the examination, her Aviation Medical Examiner (AME)

## § 67.309 Neurologic.

Neurologic standards for a third-class airman medical certificate are:

 $<sup>^2</sup>$ FAR Section 67.309, 14 CFR § 67.309, provides in pertinent part as follows:

<sup>(</sup>a) No established medical history or clinical diagnosis of any of the following:

<sup>(1)</sup> Epilepsy;

<sup>(2)</sup> A disturbance of consciousness without satisfactory medical explanation of the cause....

<sup>(</sup>b) No other seizure disorder, disturbance of consciousness, or neurologic condition that the Federal Air Surgeon, based on the case history and appropriate, qualified medical judgment relating to the condition involved, finds-

<sup>(1)</sup> Makes the person unable to safely perform the duties or exercise the privileges of the airman certificate applied for or held; or

<sup>(2)</sup> May reasonably be expected, for the maximum duration of the airman medical certificate applied for or held, to make the person unable to perform those duties or exercise those privileges.

The Administrator did not pursue denial based on epilepsy. (Reply Brief at p. 2, n.1).

diagnosed a urinary tract infection and prescribed Septra, a sulfa-based antibacterial medication. Petitioner subsequently suffered three disturbances of consciousness. As petitioner notes in her appeal, the issue here is not whether she had one or more disturbances of consciousness, but whether a satisfactory medical explanation exists to explain the cause of these neurological events.

According to the record, petitioner had taken Septra for a few days when she began to feel feverish and achy. She assumed she had the flu, since she had been exposed to it earlier that week. By the end of the week, petitioner also had chills and was vomiting. Her husband testified that on the evening of November 3, 1995, petitioner's temperature exceeded 103°. He saw her faint, fall straight backwards, and hit her head. He testified that she became "kind of rigid." He rushed her to the emergency Petitioner was sent home later that night, where a second episode occurred. Emergency room notes contain her husband's description of the second event. Petitioner was sleeping. gasped for breath, became stiff, and pulled her head back. She was unresponsive for about 15 minutes, and she then vomited. Petitioner returned to the emergency room, where a third episode occurred. Emergency room personnel describe "seizure activity" in petitioner's medical records: her lips turned blue; her body became rigid; and her mouth had to be suctioned of foamy sputum.

<sup>&</sup>lt;sup>3</sup>Dr. Hastings testified that it is not clear whether the first episode was a faint or a seizure.

Petitioner was admitted and prescribed Dilantin. An EEG performed in the hospital was abnormal, though subsequent EEGs have been normal.

Petitioner's treating neurologist, Dr. Bertha Blanchard, discharged petitioner from the hospital with the diagnosis, "symptomatic seizure secondary to Septra." Petitioner relies on Dr. Blanchard's discharge note and on the neurologist's follow-up letter to the AME, to establish a medical explanation for her seizures. Further, she argues, this medical explanation is reasonable because it is supported by medical texts such as the Physician's Desk Reference (PDR), which list "convulsions" as a possible adverse reaction to Septra. Neither petitioner's neurologist or any other expert witness testified on her behalf.

The Administrator presented the testimony of John Hastings, MD, a board-certified neurologist. Dr. Hastings has been an AME since 1975. He is a pilot, and holds a commercial airman certificate. Dr. Hastings testified that he reviewed petitioner's entire airman medical record. Dr. Hastings disagrees with Dr. Blanchard's opinion that Septra toxicity is the cause of petitioner's seizures.

Stomach and skin problems are common adverse reactions to sulfa-type drugs, and typically appear within 72 hours of taking the medication. However, Dr. Hastings explained, Septra toxicity, a type of serum sickness, is by definition a delayed reaction to the medication. According to Dr. Hastings, it usually takes three weeks for symptoms of serum sickness to

appear. Petitioner's flu-like symptoms, however, occurred within days of her taking Septra. Moreover, serum sickness typically affects the whole body, but Dr. Hastings found no support in petitioner's medical records that she experienced a systemic illness. She had no macular rash; no abnormal liver function; no recorded high fever<sup>4</sup>; and no hallucinations. The petechia observed on petitioner's eyes, arm, and tongue are tiny blood spots that were likely caused by straining during her seizures. Rashes that are clinical manifestations of serum sickness are "measles-like" -- all over the body, red, and blotchy. Further, Dr. Hastings notes, none of the physicians who examined petitioner at the hospital noted a systemic illness.<sup>5</sup>

Dr. Hastings performed an exhaustive search of medical literature regarding adverse reactions to sulfa-type drugs. He testified that seizures caused by sulfa drugs, which have been used since the 1930's, have rarely been reported in the medical literature, and in those cases he did find, the patient suffered extreme symptoms of toxicity, such as liver damage, not the mild, nonspecific symptoms described by petitioner. Thus, Dr.

<sup>&</sup>lt;sup>4</sup>Dr. Hastings also points out that, notwithstanding petitioner's report of a high fever prior to the first incident, Drs. Entriken, Hodges, Cotton, and Blanchard all noted low-grade (under 101°) fevers immediately preceding and following the second and third episodes.

<sup>&</sup>lt;sup>5</sup>Petitioner's white blood cell count, another indicia of serum sickness, was also recorded as normal in her medical records at the time of these episodes.

<sup>&</sup>lt;sup>6</sup>Many of the reported cases are distinguishable because they also involved patients with other medical problems.

Hastings testified, the medical literature does not support Dr. Blanchard's diagnosis of seizures secondary to Septra.

Dr. Hastings also rejected petitioner's reliance on the excerpt from the PDR, which lists "convulsions" as a possible adverse reaction to Septra. According to Dr. Hastings, the PDR and several other pharmacological, paramedic, and nursing textbooks submitted by petitioner are not scholarly publications based on investigative studies of patients by physicians and other researchers. The PDR contains reports compiled by the manufacturer and the FDA of reactions that may be associated with the use of a medication. Any number of sources, including patients, can make the reports.

Dr. Hastings also contacted the manufacturer of Septra, but he could find no support for petitioner's claims. Finally, Dr. Hastings testified that he also called a neuropharmacologist and two epidemiologists who are themselves neurologists specializing in epilepsy. They discussed petitioner's case, and all agreed that Septra is not a known cause of seizures.

In sum, the chance that Septra caused petitioner's seizures is, in Dr. Hastings' opinion, "very remote." Dr. Hastings concluded that petitioner's seizures are idiopathic, i.e., of

<sup>&</sup>lt;sup>7</sup>Dr. Hastings also took exception to the AME's suggestion, contained in the medical records, that high fevers may lead to seizures. According to Dr. Hastings, high fevers do not lead to isolated seizures, except in infants. Dr. Hastings testified, "I stake my reputation" on his opinion that adults cannot have febrile seizures. TR-176. In any event, Dr. Hastings noted, petitioner's temperature was not recorded as high at the time of the second and third episodes, which were, in his opinion, clearly seizures.

unknown cause. The risk of recurrence is about 30% for the first four years. After that, the risk begins to approach that of the normal population. Dr. Hastings does not believe petitioner should be considered for certification until four years have passed.

As the law judge notes in his decision, petitioner had the burden of proving an explanation for her seizures by a preponderance of the evidence. Petition of McAllister, 1 NTSB 1158, 1159 (1971). She failed to overcome that burden. She produced no expert witnesses at the hearing. Instead, she relied on letters and other unsupported statements from her treating neurologist and her AME that were contained in her medical records. The quality of her evidence simply does not compare with the evidence produced by the Administrator. Dr. Hastings' testimony was based on his 30 years of experience as a practicing neurologist, his exhaustive review of the literature, and his inquiries with both the manufacturer and experts in the field. His testimony was clearly more persuasive, logical, and in-depth than the materials relied on by petitioner. Petition of Savage,

## ACCORDINGLY, IT IS ORDERED THAT:

Petitioner's appeal is denied.

HALL, Chairman, FRANCIS, Vice Chairman, HAMMERSCHMIDT, GOGLIA, and BLACK, Members of the Board, concurred in the above opinion and order.

<sup>&</sup>lt;sup>8</sup>Petitioner's assertion on appeal that the risk of recurrence drops off drastically after the first year is not supported by this record.